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UNITED STATES PATENT & TRADEMARK OFFICE

Re: Application of: Ronald Brown MILLER, et al.

Serial No.: 10/067,451

Filed: February 5, 2002

For: **PHARMACEUTICAL FORMULATION**

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58-02

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 200231

April 4, 2002

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying PTO-1449 Form for consideration by the Examiner in connection with the examination of the above-identified patent application.

Additionally, in accordance with the provisions of 37 C.F.R. § 1.98 (d), the references cited in the attached Form PTO-1449 have been previously submitted to the PTO or cited by the Examiner during the prosecution of parent application Serial No. 09/043,321, "Pharmaceutical Formulation", filed July 27, 1998.

The Examiner's attention is also respectfully directed to the following references:

U.S. Patent No. 5,378,474 to Morella et al. (reference letter AB), U.S. 5,202,128 to Morella et al. (reference letter AC), U.S. Patent No. 5,133,974 to Paradissis et al. (reference letter AJ), U.S. Patent No. 5,330,766 to Morella et al. (reference letter BA), U.S. Patent No. 5,411,745 to Oshlack et al (reference letter BI), U.S. Patent No. 5,520,931 to Persson et al. (reference letter



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DA), WO 92/006679 (reference letter AM), WO 94/03160 (reference letter BN), 90/47732 AU (B) (reference letter BO), and 93/41654 AU(A) (reference letter BP).

Further, Applicants respectfully advise the Examiner of the following issued U.S. Patents and copending U.S. Patent Applications commonly assigned to the owners of the instant application:

U.S. Patent No. 5,478,577; "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level", issued December 26, 1995;

✓ U.S. Patent No. 5,672,360; "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations", issued September 30, 1997;

✓ U.S. Patent Application No. 08/938,898, "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level", filed September 26, 1997, withdrawn from issue;

✓ U.S. Patent Application No. 09/304,694, "Method of Treating Pain by Administering 24 Hour Oral Opioid Formulations Exhibiting Rapid Rate of Initial Rise of Plasma Drug Level", filed May 4, 1999, pending;

U.S. Patent No. 5,968,551; "Orally Administrable Opioid Formulations Having Extended Duration of Effect", issued October 19, 1999;

U.S. Patent No. 5,879,705; "Sustained Release Compositions of Morphine and a Method of Preparing Pharmaceutical Compositions", issued March 9, 1999;



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U.S. Patent No. 6,143,328; "Sustained Release Compositions of Morphine and a Method of Preparing Pharmaceutical Compositions", issued November 7, 2000;

U.S. Patent No. 5,958,459; "Opioid Formulations Having Extended Controlled Release", issued September 28, 1999;

✓ U.S. Patent No. 6,143,322; "Method Of Treating Humans With Opioid Formulations Having Extended Controlled Release", issued November 7, 2000; and

U.S. Patent No. 6,103,261; "Opioid Formulations Having Extended Controlled Release", issued August 15, 2000;

This Information Disclosure Statement is filed under 37 C.F.R. §1.97 (b), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. However, if it is determined that any fee is due, the Assistant Commissioner is hereby authorized to charge said fees to Deposit Account No. 50-0552.



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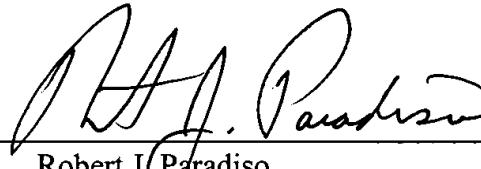
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It is respectfully requested that the references cited in the accompanying Form PTO-1449
be considered and made of record.

Respectfully Submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940

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In re application of: Ronald Brown MILLER, et al.
 Serial No.: 10/067,451
 Filed: February 5, 2002
 For: **PHARMACEUTICAL FORMULATION**

Sir:

Transmitted herewith is an Information Disclosure Statement in the above-identified application.

- Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
- Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
- No fee for additional claims is required.
- A filing fee for additional claims calculated as shown below, is required:

- Also transmitted herewith are:
 - Petition for extension under 37 C.F.R. 1.136 (in duplicate)
 - Other: Form PTO-1449

- Check(s) in the amount of **\$0.00** is/are attached to cover:
 - Filing fee for additional claims under 37 C.F.R. 1.16
 - Petition fee for extension under 37 C.F.R. 1.136
 - Other:

- The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
 - Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
 - Any patent application processing fees under 37 C.F.R. 1.17.
 - Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

Richard V. Zanzalari

Richard V. Zanzalari, Reg. No. 49, 032
 DAVIDSON, DAVIDSON & KAPPEL, LLC
 485 Seventh Avenue, 14th Floor
 New York, New York 10018
 Tel: (212) 736-1940
 Fax: (212) 736-2427

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on

April 4, 2002

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: *Richard V. Zanzalari*